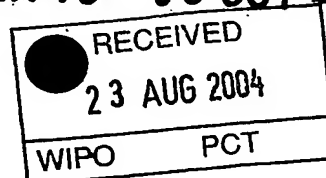


PATENT COOPERATION TREATY

PCT



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
1.P566.12PC.		
International application No.	International filing date (day/month/year)	Priority date (day/month/year)
PCT/US02/21310	01 August 2002 (01.08.2002)	12 April 2002 (12.04.2002)
International Patent Classification (IPC) or national classification and IPC		
IPC(7): A61B 17/16 and US Cl.: 606/81		
Applicant		
PRECIMED S.A.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29 August 2003 (29.08.2003)	04 August 2004 (04.08.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer McDermott or Shaver Telephone No. (703) 308-0858 <i>Sheila H. Vandy</i> Paralegal Specialist Tech. Center 3700

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description:
pages 1-15 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☒ the claims:
pages 17-21, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages 16, filed with the letter of 12 July 2004 (12.07.2004).
- ☒ the drawings:
pages 1-15, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.
- ☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US02/21310

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-38</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>6,9,10,25,26,28-31 and 33-38</u>	YES
	Claims <u>1-5,7,8,11-24,27,32</u>	NO
Industrial Applicability (IA)	Claims <u>1-38</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Please See Continuation Sheet

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

V. 2. Citations and Explanations:

Claims 1-5,7,8,11-24,27, and 32 lack an inventive step under PCT Article 33(3) as being obvious over US Patent No. 5,913,858 (Calandruccio et al.) in view of US Patent No. 6,245,074 (Allard et al) and in further view of US Patent No. 6,168,600 (Grace et al.).

Calandruccio discloses a reamer in Figures 18-21 that meets most of the limitations of the claims. The reamer includes a domed shell (2.43) with cutting sites on the outer surface (2.51). The shell has both a static insertion profile and a dynamic profile. The insertion profile has a diameter of "X" in Figure 19. The dynamic profile is circular and defined by the total diameter of the base of the shell (2.43), as seen in Figure 18. Calandruccio explains that the insertion profile is smaller than the dynamic profile (column 9, line 24). The reamer also has a means for being connected to a rotary tool (column 6, lines 53-56).

Calandruccio does include "first portions" that are generated about a first radius with a center that lies on the rotational axis (2.57) of the device. These first portions describe the diameter of the shell and are bladed. Calandruccio fails to include second portions that have a radius center lying away from the rotational axis (2.57). Allard discloses a reamer that is in the form of a domed shell with cutting sites (26) on the outer surface (24), as best shown in Figure 4. The cutting head (14) has first portions (28) and second portions (30). The center of the radius of the second portions (30) lies away from the center of the radius of the first portions (28). The second portions are concave and generally circular or parabolic. There is a plurality of first and second curved portions. Allard teaches this structure of a cutting shell (14) allows a surgeon to view the bone while in the reamer is in operation (column 1, lines 36-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include second portions in the shell of Calandruccio, as Allard teaches that the second portions allow a surgeon to view the bone during operation.

The combined Calandruccio and Allard device fails to form the cutting sites as apertures that allow debris to pass into a cavity of the shell. Grace discloses another reamer with a cutting domed shell that is connected to a rotary tool. Grace teaches that cutting sites of acetabular reamers are known in the art to be formed as apertures. It would have been

INTERNATIONAL PRELIMINARY EXAMINATION REPORTInternational application
PCT/US02/21310**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

obvious to one of ordinary skill in the art to substitute apertures for the cutting sites of Calandruccio and Allard, since this is simply another way to form an acetabular reamer. The teaching of Grace is the important thing here, not whether the components of the devices can be physically combined.

Grace illustrates several different variations of keyed plates (23) that align the shell (11) with the rotary tool holder (30). Figure 5 shows an embodiment with a pair of bars (65) on either side of the shell, where each bar has a pair of "keyed male centering members" (77,77'). This embodiment also anticipates claim 27, as the pair of bars have opposing female notches (67). It would have been obvious to one of ordinary skill in the art to form the mounting means of the combined Calandruccio, Allard, and Grace device as a keyed aperture, because Grace teaches that this type of connection has many advantages, such as visibility, interchangeable with different drivers, and bone chips can be removed easily (column 6, lines 45-65).

Claims 6,9,10,25,26,28-31, and 33-38 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest certain configurations of connections means on acetabular reamers.

Claims 1-38 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry, specifically for the purpose of orthopedic surgery.